IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A., and BAUSCH HEALTH IRELAND LTD., Plaintiffs, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC and AMNEAL EU, LIMITED, Defendants.	Case No. 1:24-CV-04607-JFM
SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A., and BAUSCH HEALTH IRELAND LTD., Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC. and ZYDUS PHARMACEUTICALS LIMITED, Defendants.	Case No. 1:24-CV-09512-JFM
SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A., and BAUSCH HEALTH IRELAND LTD., Plaintiffs, v. CIPLA LIMITED and CIPLA USA INC., Defendants.	Case No. 1:24-CV-10213-JFM

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PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR DENIAL OR DEFERRAL UNDER RULE 56(d)

I. Introduction

Defendants Amneal Pharmaceuticals of New York, LLC, Amneal EU, Limited, Zydus Lifesciences Ltd., Zydus Pharmaceuticals (USA) Inc., Cipla Ltd. and Cipla USA, Inc. ("Defendants") have moved for summary judgment ("MSJ"), requesting a ruling that "each of the asserted patent claims [is] invalid as obvious based on collateral estoppel" based on *Salix Pharm., Ltd. v. Norwich Pharm., Inc.*, No. CV 20-430-RGA, 2022 WL 3225381 (D. Del. Aug. 10, 2022), *aff'd* 98 F.4th 1056 (Fed. Cir. 2024) ("*Norwich I*").[1] Dkt. 113-2 at 1.

As discussed in the accompanying declaration of Michael J. Abernathy ("Abernathy Decl."), however, this case is still in **fact discovery**, and the parties have yet to begin **expert discovery**. Abernathy Decl. ¶¶ 3, 5. Defendants filed the motion prematurely, and the Court may consider it only after Salix has had a fair opportunity to discover relevant evidence. *See* Fed. R. Civ. P. 56(d); *Doe v. Abington Friends Sch.*, 480 F.3d 252, 257 (3d Cir. 2007) ("*Abington*").

Federal Rule of Civil Procedure 56(d) contemplates this exact situation—where a party moves for summary judgment before the non-movant has a full and fair opportunity to develop the record to show genuine disputes of material fact—

[1] Norwich Pharmaceuticals Inc, the defendant in *Norwich I*, did not join the motion.

and provides a mechanism to file a motion that supersedes the summary judgment motion.[2] "District courts usually grant properly filed Rule 56[(d)] motions **as a matter of course**." *Abington*, 480 F.3d at 257 (citing *St. Surin v. Virgin Islands Daily News, Inc*., 21 F.3d 1309, 1314 (3d Cir. 1994)).[3] "And whatever its decision, it is **improper** for a district court to rule on summary judgment without first ruling on a pending Rule 56[(d)] motion." *Id.*

The Court should grant Salix's Rule 56(d) motion and deny or defer considering Defendants' MSJ until at least thirty days after expert discovery concludes.[4]

II. Background

A. Procedural History

Defendants filed their MSJ on July 11, 2025, before the close of fact discovery. Dkt. 113. Fact discovery was set to close on July 18, 2025, but the Court granted the parties' joint request to take several depositions after July 18, 2025, along

[2] In 2010, the subparagraph lettering of Rule 56 changed. Relief under 56(d) was previously under 56(f). Thus, pre-2010 cases (including some cited herein) discuss Rule 56(f).

[3] Unless stated otherwise, all emphases added.

[4] Section 9 of this Court's Policies and Procedures – General Guidance and Civil Matters states parties may file only "one single Rule 56 motion" "absent leave." Salix respectfully requests this Rule 56(d) motion not be considered as Salix's "one single Rule 56 motion" under Section 9, or in the alternative, the Court preemptively grant Salix leave to file a second substantive motion for summary judgment after the close of expert discovery, should Salix identify any issues ripe for summary judgment consideration.

with a three-week extension to expert report deadlines. Dkt. 114.[5] Opening expert reports are due September 3, 2025; rebuttal expert reports are due October 8, 2025; reply expert reports are due October 29, 2025; and the deadline to conclude all expert discovery, including depositions, is December 12, 2025. *Id*. Salix's opposition to Defendants' MSJ is due August 4, 2025, more than four months before the close of expert discovery. Dkt. 115.

B. Claim Differences

Defendants' motion is premised on collateral estoppel. But Defendants acknowledge the claims at issue in this case differ from the claims at issue in *Norwich I*. Salix addresses three differences for purposes of this Rule 56(d) Motion:

- In this case, claim 6 from asserted U.S. Patent No. 11,564,912 ("'912 patent") requires "wherein the reduction of the one or more symptoms is achieved following **7 days after the administration of rifaximin**," and claim 3 of asserted U.S. Patent No. 11,779,571 ("'571 patent") requires "wherein the reduction of bloating is achieved following **7 days after the administration of rifaximin**." Dkt. 113-3 at Da0040, Da0080. In contrast, claim 2 of U.S. Patent No. 8,309,569 ("'569 patent"), which was at issue in *Norwich I*, required "wherein the durability of response

[5] Docket numbers cited are for the Amneal action, Case no. 24-cv-04607.

comprises about **12 weeks of adequate relief of symptoms**." *Id.* at Da0219.

- All claims of the '571 patent require "[a] method **of treating bloating** associated with diarrhea-predominant irritable bowel syndrome," whereas claim 3 of U.S. Patent No. 10,765,667 ("'667 patent")—asserted in *Norwich I*—is directed to "[a] method **of treating one or more symptoms** of irritable bowel syndrome (IBS)" wherein "the IBS is diarrhea-predominant IBS." Dkt. 113-3 at Da0196.
- The claims of asserted U.S. Patent Nos. 8,193,196, 8,518,949, 8,741,904, 9,271,968, and 10,703,763 (collectively, the "Polymorph Patents") are directed to rifaximin polymorphic **forms δ, ε**, or a combination of the two. Abernathy Decl. ¶ 7. Rifaximin polymorphic **form β**, which was at issue in *Norwich I* and held obvious, is claimed in a different family of patents from the Polymorph Patents and has different properties than polymorphic forms at issue in this matter. Dkt. 113-2 at 7.

III. Legal Standard

Federal Rule of Civil Procedure 56(d) states when a party moves for summary judgment, "[i]f a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1)

defer considering the motion or deny it; (2) allow time to . . . take discovery; or (3) issue any appropriate order."

In *Abington*, the Third Circuit recognized "it is well established that a court is obliged to give a party opposing summary judgment an adequate opportunity to obtain discovery." 480 F.3d at 256–57 (citing *Dowling v. City of Philadelphia*, 855 F.2d 136, 139 (3d Cir. 1988)). "This is necessary because, by its very nature, the summary judgment process presupposes the existence of an adequate record." *Id.* (citing Fed. R. Civ. P. 56(c) and *Anderson* v. *Liberty Lobby, Inc.,* 477 U.S. 242, 257 (1986) (explaining the non-moving party's burden at summary judgment rests on the assumption that the party "had a full opportunity to conduct discovery")).

In this vein, the Supreme Court has explained that "[a]ny potential problem with . . . premature [summary judgment] motions can be adequately dealt with under Rule 56[(d)]." *Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1986). "[I]f the non-moving party believes that additional discovery is necessary, the proper course is to file a motion pursuant to Rule 56[(d)]." *Abington*, 480 F.3d at 257 (citing *Dowling*, 855 F.2d at 139).

When filed, "[d]istrict courts usually grant properly filed Rule 56[(d)] motions **as a matter of course**." *Abington*, 480 F.3d at 257 (quoting *St. Surin*, 21 F.3d at 1314). "If discovery is incomplete in any way material to a pending summary judgment motion, a district court is justified in not granting the motion." *Id.* (citing

Miller v. Beneficial Mgmt. Corp., 977 F.2d 834, 845–46 (3d Cir. 1992)); *see also Shelton v. Blesdoe*, 775 F.3d 554, 568 (3d Cir. 2015) ("If discovery is incomplete, a district court is rarely justified in granting summary judgment.").

Third Circuit "case law makes clear that a Rule 56[(d)] motion must identify with specificity what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not previously been obtained." *Lunderstadt v. Colafella*, 885 F.2d 66, 71 (3d Cir. 1989).

IV. Argument

A. Defendants' Motion Requires Resolving Certain Issues of Fact.

Defendants move for summary judgment based on collateral estoppel (also referred to as issue preclusion). *See* Dkt. 113. They assert (erroneously) the differences among the claims at issue in *Norwich I* and those at issue in this case are immaterial and do not bear on the question of obviousness already adjudicated in *Norwich I*. *Id.* at 113-2.

The Federal Circuit has admonished that courts should not treat the claims previously invalidated as prior art. *Interconnect Plan. Corp. v. Feil*, 774 F.2d 1132, 1137 (Fed. Cir. 1985). "A domino approach in which each successively narrower claim is compared with the one before it, not with the prior art, is inappropriate since it improperly gives prior-art effect to the subject matter of an invalid claim." *Id*. (citing *Bourns, Inv. v. United States*, 537 F.2d 486, 493 (Ct. Cl. 1976)). Further, "it

is well settled that each claim of a patent is entitled to a presumption of validity and is to be treated as a complete and independent invention." *Id.* Defendants must show "the additional elements recited in the unadjudicated claims do not distinguish the claimed combination as a whole from the prior art." *Bourns*, 537 F.2d at 493.

When determining whether additional claim language affects an obviousness analysis, "an inquiry into the identity of the validity issue is more properly phrased in terms of the **factual inquiries** mandated by *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966), as a **prerequisite** to such a validity determination." *Interconnect*, 774 F.2d at 1136; *see also Bourns,* 537 F.2d at 493 ("[I]t is clear that the differences revealed by such comparisons must be evaluated . . . in terms of the *Graham* issues."). If "the unadjudicated claims present any new issues," then "to afford due process" there must be a "a trial on the merits." *Id.*

While "obviousness presents an ultimate legal question," it has "numerous underlying factual findings." *Cyntec Co., Ltd. v. Chilisin Elecs. Corp.*, 84 F.4th 979, 984 (Fed. Cir. 2023) (citing, *inter alia*, *Graham*). "These factual questions include: "(1) the scope and content of the prior art, (2) differences between the prior art and the claims at issue, (3) the level of ordinary skill in the pertinent art, and (4) the presence of objective indicia of nonobviousness such as commercial success, long felt but unsolved needs, failure of others, and unexpected results." *Id.* "Whether a skilled artisan would have been motivated to combine references is also a fact

question[.]" *Id.* "The presence or absence of a reasonable expectation of success is also a question of fact." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1366 (Fed. Cir. 2016).

Since Defendants' motion is premised on collateral estoppel based on the obviousness determinations in *Norwich I*, this Court cannot resolve Defendants' motion without considering the underlying questions of fact in an obviousness determination.

B. Salix Has Sufficiently Described the Essential Underlying Facts It Seeks to Prove to Defeat Summary Judgment.

Salix intends to introduce expert testimony on underlying factual issues relevant to resolving whether the additional elements recited in the unadjudicated claims distinguish the claimed combinations as a whole from the prior art.

For example, Salix intends to seek expert discovery on the significance of the "wherein the reduction of the one or more symptoms is achieved following **7 days after the administration of rifaximin**" limitation and how it affects the underlying factual findings relevant to the obviousness determination. Abernathy Decl. ¶¶ 9-13, 16-18.

Defendants assert, without citation or support, that this limitation is not materially different from the "wherein the durability of response comprises about **12 weeks of adequate relief of symptoms**" limitation in the claims in *Norwich I*. Dkt. 113-2 at 14. However, Salix intends to proffer expert testimony that the "7 days

limitation" at issue here relates to the **amount of time before the patient begins feeling relief during treatment**, while the "durability of response" claim in *Norwich I* relates to the **duration during which the patient feels relief after treatment**. Abernathy Decl. ¶ 16. In addition, the shared specification of the patents asserted in this case and those asserted in *Norwich I* ("IBS-D Shared Specification") defines "durability of response" as "adequate relief of symptoms after removal of treatment, continuous adequate relief of symptoms after removal of treatment." Dkt. 113-3 at 13:27-34. It explains "[a] response by a subject may be considered durable, for example, if they have a response of the rifamycin class antibiotic after removal from treatment." *Id.*; *see also* Abernathy Decl. ¶ 16, Ex. A to Abernathy Declaration (*Norwich I* Tr. 518) (Salix's expert Dr. Schoenfeld testifying in *Norwich I* that durability of response refers to "continu[ing] to have adequate relief of [] symptoms beyond completing the antibiotic course. . . . for a certain number of weeks after I complete 14 days of antibiotics."); *id*. at 814 (Dr. Schoenfeld testifying a skilled artisan would understand this term means "once the antibiotic is stopped, any relief of IBS-D symptoms that occur while on the antibiotic does not immediately go away. When you complete 14 days of treatment, you continue to have relief of your IBS-D symptoms."). Salix anticipates its expert will opine (i) the limitation requiring reduction of treatment following 7 days for the claims in this case occurs during treatment, not after removal of treatment, differentiating the 7 days limitation from

the 12 week durability of response limitation at issue in *Norwich I* and (ii) the prior art combination the district court relied on in *Norwich I* did not disclose or suggest the "wherein the reduction of the one or more symptoms is achieved following 7 days after the administration of rifaximin" limitation. Abernathy Decl. ¶¶ 7, 9, 16, 18.

Indeed, the 7 day limitation was not discussed at trial in *Norwich I,* and the district court's opinion in that case nowhere mentions that limitation in its obviousness analysis. *Id*. ¶ 7. Salix's experts will offer opinions on how the 7 day limitation makes the claims as a whole patentable over the prior art, including whether the prior art discloses this limitation in the context of the claim and why a skilled artisan would not have been motivated to combine the asserted prior art in *Norwich I* with a reasonable expectation of success to render those claims obvious. *Id*. ¶¶ 9-13. The parties have yet to submit expert reports on these issues, and they will not complete expert discovery until December 12, 2025. *Id*. ¶ 4. Accordingly, the MSJ is premature.

Additionally, Salix intends to offer expert testimony on the significance of "treating bloating associated with diarrhea-predominant irritable bowel syndrome" as opposed to the broader feature of "one or more symptoms of [diarrhea-predominant IBS]." *Id*. ¶ 14, 18. Defendants assert, again without citation or support, that bloating is a symptom of irritable bowel syndrome. Dkt. 113-2 at 14.

Salix, however, expects to offer expert testimony that a skilled artisan would have considered bloating a discrete condition from irritable bowel syndrome or "diarrhea-predominant IBS" under the governing classification system known as Rome III. *Id.* ¶ 14. Salix's expert also will consider dependent claim 2 of the '667 Patent, which recites that "one or more [of the IBS] symptoms are selected from one or more of cramping, pain, diarrhea, constipation, lumpy stool, watery stool, frequent stool production, abdominal pain, abdominal discomfort and urgency." Dkt. 113-3 at Da0196 at 46:34-38; *see also* Abernathy Decl. ¶ 15.

Salix's expert also will consider how the IBS-D Shared Specification teaches bloating as distinct from "symptoms of irritable bowel syndrome" or diarrhea-predominant IBS. Abernathy Decl. ¶ 14. For example, the IBS-D Shared Specification states "[i]n one embodiment, symptoms comprise one or more of overall BD [bowel disease] symptoms **or** bloating." Dkt. 113-3 at Da0174 at 2:44-45. In the "Description of the Drawings," the IBS-D Shared Specification again recognizes the distinction, with Figure 1 "show[ing] a graph of continuous adequate relief of IBS symptoms during non-treatment follow-up," *id.* at Da0177 at 7:20-21, while "Fig[ure] 2 shows a graph of continuous adequate relief of bloating symptoms during non-treatment follow-up." *Id.* at 7:22-23. Likewise, Figures 4 and 5 graph "results of adequate relief of IBS symptoms" and "results of adequate relief of bloating symptoms" separately. *Id.* at 7:26-28. The IBS-D Shared Specification

also discusses "adequate relief of IBS symptoms and/or adequate relief of IBS symptom of bloating." Da0185 at 23:40-42. Table 3 has separate sections for "IBS Symptoms" and a "Bloating Symptom." *Id.* at 24:40-50.

Bloating was not discussed in detail at trial in *Norwich I*, and the district court's opinion says nothing substantive about bloating in its findings of fact or obviousness analysis. Abernathy Decl. ¶¶ 7, 18. Salix's expert will offer opinions on how the "bloating associated with diarrhea-predominant irritable bowel syndrome" limitation makes the claims as a whole patentable over the prior art, including whether the prior art discloses the bloating limitation and why a skilled artisan would not have been motivated to combine the asserted prior art in *Norwich I* with a reasonable expectation of success to render those claims obvious. *Id.* ¶¶ 9-14, 18.

Further, rifaximin polymorphic **form β**, which was at issue in *Norwich I* and held obvious, is from a different family of patents than the Polymorph Patents that claim rifaximin polymorphic **forms δ and ε**, or a combination of the two. Dkt. 113-2 at 20. Defendants once again assert, without citation or support, that the different polymorphs are a "distinction without a difference." *Id.* Salix's experts will consider how the Polymorph Patents' specification defines "Polymorphs" and "polymorphic forms" as "the occurrence of different crystalline forms of a single compound in distinct hydrate status, e.g., a property of some compounds and

complexes." Abernathy Decl. ¶ 8. Thus, "polymorphs are distinct solids sharing the same molecular formula, yet **each polymorph may have distinct physical properties** . . . such as solubility profiles, melting point temperatures, hygroscopicity, particle shape, density, flowability, compatibility and/or x-ray diffraction peaks." Dkt. 113-3 at Da0022 at 10:31-41. Salix's experts will opine on the differences between the different polymorphs at issue here and the one at issue in *Norwich I* and how those differences, including the distinct physical properties, affect the obviousness analysis. Abernathy Decl. ¶¶ 8, 9-13.

Although the district court in *Norwich I* made findings related to polymorph **β**, it did not consider other polymorphs such as **δ and ε:** "I think the evidence shows that a POSA would have a reasonable expectation of success in characterizing the **polymorph β, as opposed to the other forms of rifaximin**." *Norwich I*, 2022 WL 3225381, at *7. "Although Norwich's evidence failed to show that β was produced each and every time rifaximin was prepared according to Cannata, it did strongly suggest that polymorph β is a commonly produced polymorph and the most stable form of rifaximin." *Id*. The record is incomplete as to whether δ, ε, or a combination of the two, are (1) commonly prepared according to Cannata, (2) prepared as commonly as β, and (3) as stable as β. Indeed, the district court's findings in *Norwich I* imply the polymorphs at issue here are not as stable as β, which the district court characterized as the "most stable form." *Id*. Salix's experts will offer opinions

on how the δ and ε polymorphs are patentable over the prior art, including whether the prior art discloses these polymorphs and why a skilled artisan would not have been motivated to combine the asserted prior art in *Norwich I* with a reasonable expectation of success to render those claims obvious. Abernathy Decl. ¶¶ 8-13.

* * *

Expert testimony on any of these issues would preclude summary judgment. *See Lunderstadt*, 885 F.2d at 71; *Chek-Med Sys., Inc. v. PMT Corp.*, No. 1:09-CV-174, 2011 WL 13177569, at *5 (M.D. Pa. Apr. 14, 2011) (staying briefing on summary judgment motion until conclusion of expert discovery where "Defendants have identified the particular information they seek from Plaintiff, notably, the opportunity to conduct expert discovery as to Dr. Naiman's opinions regarding infringement of PMT's product based on the Court's construction of the disputed claims, and the opportunity to consult their own experts in order to challenge the test methods and conclusions arrived at by Mr. Cassely and Chemir Analytical").

In *Otsuka Pharmaceutical Co. v. Sandoz Inc.*, this Court granted a Rule 56(d) motion "because the parties remain in the early phases of pretrial factual discovery." No. CV 15-1716 (JBS/KMW), 2015 WL 7888710, at *1 (D.N.J. Sept. 9, 2015). This Court explained how "the fact that Sandoz produced little to no expert analysis in connection with its motion for summary judgment underscores the early stage of this litigation, and the premature nature of its requested relief." *Id.* The same is true

here, and Defendants' MSJ regarding the significance of the claim differences and their effect on the obviousness analysis is unsupported by expert analysis. Just as in *Otsuka*, the Court should grant Salix's Rule 56(d) motion because the MSJ is premature.

C. Salix Has Diligently Sought Discovery.

As fact discovery concludes, Salix has served at least 75 requests for production, 17 interrogatories, and 25 requests for admission on each defendant.[6] Abernathy Decl. ¶ 3. Salix has collected and produced 100,916 documents, while Defendants have produced 3,313 documents in response to Salix's requests.[7] *Id.* As of July 23, 2025, Salix has taken two fact depositions of Defendants and defended three fact depositions.[8] *Id.* Salix received invalidity contentions on August 22, 2024 and March 13, 2025. Salix served responses on October 7, 2024 and April 10, 2025. *Id.*

Despite Salix's diligence in uncovering evidence in fact discovery, expert discovery has yet to begin. *Id.* ¶ 5. Abiding by the scheduling order, Salix's experts

[6] Salix has served a total of 17 interrogatories on each defendant; 76 requests for production on Zydus; 75 requests for production on each of Amneal and Cipla; and 25 requests for admission on each defendant. Abernathy Decl. ¶ 3.
[7] Salix produced 246 documents to Amneal only; 223 documents to Cipla only; 211 documents to Zydus only; and 100,236 documents to all consolidated defendants. *Id.*
[8] Based on the current schedule, Salix will take at least four additional depositions and defend three additional depositions. *Id.*

have only just begun reviewing the still-developing evidentiary record. *Id.* Salix has had no opportunity to review and respond to Defendants' forthcoming invalidity reports. *Id*. Salix has had no opportunity to cross examine Defendants' experts regarding the factual issues discussed in Section IV.B, *supra*, including—for example—whether the new limitations at issue here are found in the prior art, whether skilled artisans would have been motivated to combine the prior art to arrive at the claimed inventions as a whole, and whether skilled artisans would have had a reasonable expectation of success at arriving at the claimed inventions. *Id.* The discovery Salix seeks is forthcoming and could not have been obtained earlier. *See generally Carroll v. Dep't of Transp.*, No. 1:22-CV-00242, 2024 WL 3522030, at *9 (M.D. Pa. July 24, 2024) (denying portion of motion for summary judgment as premature because "[t]he Court cannot resolve the issue of sovereign immunity at this stage when expert testimony on the existence of a dangerous condition is forthcoming.").

V. Conclusion

For the reasons discussed above and in the accompanying Abernathy Declaration, the Court should not reach the merits of Defendants' MSJ. Instead, it should deny or defer consideration of the MSJ under Rule 56(d) until at least thirty days after expert discovery concludes.

Dated: July 23, 2025

RESPECTFULLY SUBMITTED,

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